

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PRESTA ET AL.

DECEMBER 19, 2001

Examiner:

UNKNOWN

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Filed:

10/027,736

Group Art Unit: Docket:

UNKNOWN 11669.92US01

APR 1 5 2002

Confirmation No.:

9756

Title:

NON-HUMAN Fc RECEPTORS AND METHODS OF USE

TECH CENTER 1600/2900

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence and the paper(s), as described herein, are being deposited in the United States Postal Service, as first class mail, with sufficient postage, in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231, April 8, 2002.

Commissioner for Patents Washington, D.C. 20231

Sir:

We are transmitting herewith the attached:

☐ Transmittal Sheet in duplicate containing Certificate of Mailing

Supplemental Information Disclosure Statement, Form 1449, 36 References

Return postcard

Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers or any future reply, if appropriate. Please charge any additional fees or credit overpayment to Deposit Account No. 13-2725. A duplicate of this sheet is enclosed.

MERCHANT & GOULD P.C. P.O. Box 2903, Minneapolis, MN 55402-0903 612.332.5300

Reg. No.: 36,848 KKowalchyk:sab

Name: Katherine M. Kowalchyk



PATENT

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Applicant:

PRESTA ET AL.

Examiner:

UNKNOWN

APR 1 5 2002

Serial No.:

10/027,736

Group Art Unit:

UNKNOWN TECH CENTER 1600/290

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NON-HUMAN Fc RECEPTORS AND METHODS OF USE

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By: Shery A. Boertoom

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT (37 C.F.R. § 1.97(b))

Commissioner for Patents Washington, D.C. 20231

Dear Sir:

With regard to the above-identified application, the items of information listed on the enclosed Form 1449 are brought to the attention of the Examiner.

This statement should be considered because it is submitted before the mailing date of a first Office Action on-the-merits. Accordingly, no fee is due for consideration of the items listed on the enclosed Form 1449.

In accordance with 37 C.F.R. §1.98(a)(2), a copy of each document or other information listed on the enclosed Form 1449 is provided.

No representation is made that a reference is "prior art" within the meaning of 35 U.S.C. §§ 102 and 103 and Applicants reserve the right, pursuant to 37 C.F.R. § 1.131 or otherwise, to establish that the reference(s) are not "prior art." Moreover, Applicants do not represent that a reference has been thoroughly reviewed or that any relevance of any portion of a reference is intended.

Consideration of the items listed is respectfully requested. Pursuant to the provisions of M.P.E.P. 609, it is requested that the Examiner return a copy of the attached Form 1449, marked as being considered and initialed by the Examiner, to the undersigned with the next official communication.



Please charge any additional fees or credit any overpayment to Deposit Account No. 13-

Respectfully submitted,

MERCHANT & GOULD P.C. P.O. Box 2903 Minneapolis, Minnesota 55402-0903

(612) 332-5300

Date: <u>April 8, 2002</u>

Katherine M. Kowalchyk

Reg. No. 36,848

KMK:sab

ORM 1449* O P P CORMATION DISCLOSURE STATEMENT	Docket Number: 11669.92US01	Application Numb APR 1 5 2002
IN AN APPLICATION	Applicant: PRESTA ET AL.	TECH CENTER 1600/2900
APR 1 2 2002 (Use several sheets if necessary)	Filing Date: 12/19/01	Group Art Unit: UNKNOWN

		1	U.S. PATENT DOCUMEN	TS			
EXAMINER INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
		FO	REIGN PATENT DOCUM	ENTS			
	DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
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			and Pharmacodynamics of Pharmacology and Expen				
			neutic effects of a humanize arthritis (CIA) in rhesus n				
	Clynes, R. et al., "Fc rec 95, No. 2, pp. 652-656 (red in passive and active 8)	immunity to mela	anoma", <i>Proc. Nata</i>	l. Acad. Sci. U	<i>ISA</i> , Vol.
			of Administration of a Hulogy, Vol. 92, No. 2, pp. 1		Monoclonal Antibo	ody, HM6G, i	n
	Ghetie, V. et al., "Multip of Immunology, 18:739-		e Major Histocompatibilit	y Complex Class	I-Related Recepto	r FcRn", Ann	ual Reviev
	Glennie, M. et al., "Clin	ical trials of ant	ibody therapy", Immunolo	ogy Today, Vol. 2	21, No. 8, pp. 403-4	411 (August 2	.000)
			ynamics of 5c8, a Monoc ournal of Pharmacology a				
	Hamawy, M. et al., "Imr FN18", Transplantation,	nunotoxin FN1 Vol. 72, No. 3	8-CRM9 Induces Stronge, pp. 496-503 (August 15,	r T Cell Signalin 2001)	g Than Unconjuga	ted Monoclor	al Antiboo
			safety of mepolizumab (S Allergy and Clinical Imm				
			mmalian Cells, VII. Indu			utants in Chir	nese
	Hallister Cells , Froc. N	an, Acaa, Sci. (USA, Vol. 60, No. 4, pp. 1	275-1281 (Augu:	St 1908)		

EXAMINER	DATE CONSIDERED

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Sheet 2 of 3

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FORM_1449*	
OIPE	NFORMATION DISCLOSURE STATEMENT

IN AN APPLICATION

(Use several sheets if necessary)

Docket Number: Application NumAcPR 1 5 2002

Applicant: PRESTA ET AL.

TECH CENTER 1600/2900

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	Küester, H. et al., "Characterization and Expression of the Gene for the Human Fc Receptor γ Subunit", <i>The Journal of Biological Chemistry</i> , Vol. 265, No. 11, pp. 6448-6452 (April 15, 1990)
	Kurucz, I. et al., "Bacterially expressed human FcγRIIb is soluble and functionally active after in vitro refolding", <i>Immunology Letters</i> , 75:33-40 (2000)
	Lehrnbecher, T. et al., "Variant Genotypes of the Low-Affinity Fcy Receptors in Two Control Populations and a Review of Low-Affinity Fcy Receptor Polymorphisms in Control and Disease Populations", <i>Blood</i> , Vol. 94, No. 12, pp. 4220-4232 (December 15, 1999)
	Lin, Y. et al., "Preclinical Pharmacokinetics, Interspecies Scaling, and Tissue Distribution of a Humanized Monoclonal Antibody against Vascular Endothelial Growth Factors", <i>The Journal of Pharmacology and Experimental Therapeutics</i> , Vol. 288, No. 1, pp. 371-378 (1999)
	Maxwell, K. et al., "Crystal structure of the human leukocyte Fc receptor, FcγRIIa", Nature Structural Biology, Vol. 6, No. 5, pp. 437-442 (May 1999)
	Mihara, M. et al., "Hurhanized Antibody to Human Interleukin-6 Receptor Inhibits the Development of Collagen Arthritis in Cynomolgus Monkeys", Clinical Immunology, Vol. 98, No. 3, pp. 319-326 (March 2001)
	Mordenti, J. et al., "Comparisons of the Intraocular Tissue Distribution, Pharmacokinetics, and Safety of ¹²⁵ I-Labeled Full-Length and Fab Antibodies in Rhesus Monkeys Following Intravitreal Administration", <i>Toxicologic Pathology</i> , Vol. 27, No. 5, pp. 536-544 (September-October 1999)
	Mourad, G. et al., "Humanized IgG1 and IgG4 Anti-CD4 Monoclonal Antibodies", <i>Transplantation</i> , Vol. 65, No. 5, pp. 632-641 (March 15, 1998)
	Ory, P. et al., "Characterization of Polymorphic Forms of Fc Receptor III on Human Neutrophils", <i>The Journal of Clinical Investigation</i> , Vol. 83, No. 5, pp. 1676-1681 (May 1989)
	Ory, P. et al., "Sequences of Complementary DNAs that Encode the NA1 and NA2 Forms of Fc Receptor III on Human Neutrophils", <i>The Journal of Clinical Investigation</i> , Vol. 84, No. 5, pp. 1688-1691 (November 1989)
	Poston, R. et al., "Effects of Humanized Monoclonal Antibody to Rhesus CD11a in Rhesus Monkey Cardiac Allograft Recipients", <i>Transplantation</i> , Vol. 69, No. 10, pp. 2005-2013 (May 27, 2000)
	Radaev, S. et al., "The Structure of a Human Type III Fcγ Receptor in Complex with Fc", The Journal of Biological Chemistry, Vol. 276, No. 19, pp. 16469-16477 (May 11, 2001)
	Ravetch, J. et al., "IgG Fc Receptors", Annual Review of Immunology, Vol. 19:275-290 (2001)
	Reichert, J., "Monoclonal antibodies in the clinic", Nature Biotechnology, Vol. 19, No. 9, pp. 819-822 (September 2001)
	Richter, W. et al., "Animal Pharmacokinetics of the Tumor Necrosis Factor Receptor-Immunoglobulin Fusion Protein Lenercept and Their Extrapolation to Humans", <i>Drug Metabolism and Disposition</i> , Vol. 27, No. 1, pp. 21-25 (January 1999)
,	Sampson, J. et al., "Unarmed, tumor-specific monoclonal antibody effectively treats brain tumors", <i>PNAS</i> , Vol. 97, No. 13, pp. 7503-7508 (June 20, 2000)

		
EXAMINER		DATE CONSIDERED

Molecular Immunology, Vol. 38, No. 1, pp. 1-8 (January 2001)

Sautès, C., "Structure and Expression of Fc Receptors (FcR)", Cell-Mediated Effects of Immunoglobulins, Chap. 2, pp. 29-66

Schuurman, J. et al., "The inter-heavy chain disulfide bonds of IgG4 are in equilibrium with intra-chain disulfide bonds",

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APR 1 2 2002

INFORMATION DISCLOSURE STATEMENT

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APR 1 5 2002

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HADEMAN	Shinkura, H. et al., "Safety and kinetic properties of a humanized antibody to human interleukin-6 receptor in healthy non-human primates", <i>Toxicology</i> , 122:163-170 (October 19, 1997)
	Sondermann, P. et al., "Crystal structure of the soluble form of the human Fcγ-receptor IIb: a new member of the immunoglobulin superfamily at 1.7 Å resolution", <i>The EMBO Journal</i> , Vol. 18, No. 5, pp. 1095-1103 (March 1, 1999)
	Sondermann, P. et al., "The 3.2-Å crystal structure of the human IgG1 Fc fragment-FcyRIII complex", Nature, 406:267-273 (July 20, 2000)
	Spiegelberg, H., "Biological Activities of Immunoglobulins of Different Classes and Subclasses", Advances in Immunology, 19:259-294 (1974)
	van der Pol, W. et al., "IgG receptor IIa alleles determine susceptibility and severity of Guillain-Barré syndrome", Neurology, Vol. 54, No. 8, pp. 1661-1665 (April 25, 2000)
	van Dijk, M. et al., "Human antibodies as next generation therapeutics", Current Opinion in Chemical Biology, 5:368-374 (2001)
	Waurzyniak, B. et al., "In Vivo Toxicity, Pharmacokinestics, and Antileukemic Activity of TXU (Anti-CD7)-Pokeweed Antiviral Protein Immunotoxin", Clinical Cancer Research, Vol. 3, No. 6, pp. 881-890 (June 1997)



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